

REMARKS

Applicant thanks the Examiner for carefully considering this application. Please reconsider the application in view of the following remarks.

Claim Amendments

Claims 1-4, 8-9 have been amended to correct spelling errors or to clarify the invention recited. No amendment is made to claims 5-7 and 10. No new matter is introduced by these amendments.

Amendments to the Specification

Specification has been amended to correct typographic errors spelling errors or to clarify the invention, i.e., “dose” is changed to “portion” (in Chinese traditional medicine, dose means “prescribed to be taken at one time.”), “abstraction” is changed to “extraction.” No new matter is introduced by these amendments.

35 U.S.C. § 103 rejections

Claims 1-10

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being obvious over the combination of Zuo (WO 01/76613 A1), Kim (US 4, 696,818), Wen (US 5,198,230), Zhou(US 6,416,806), Oh(KR 2000072102), and Chang et al (US 5,552,404). For reasons set forth below, this rejection is respectfully traversed.

To reach a proper determination under 35 U.S.C. § 103, the examiner must step backward in time and into the shoes worn by the hypothetical “person of ordinary skill in the art” when the invention was unknown and just before it was made. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art alone, without the guidance of the Applicant’s application. Applicant respectfully submits that by relying on four or more references to reject the claims of the present

Application No.: 10/518,728
Docket No. SZ001-04

invention, the Examiner has committed impermissible hindsight reconstruction based on the road map provided by the present invention.

Even if one assumes that these prior art references are properly combinable, they still fail to render the claims obvious because they failed to teach all the claim limitations. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. (*In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); *see also*, MPEP § 2143 - § 2143.03).

The present invention is directed to a Chinese medicine preparation for curing an withdrawal symptom of addictive drug reliers, every 100 portions of the medicine comprises: Panax ginseng root 68-205g; Aconitum carmichaeli Debx root 75-225g; Cinnamomum cassia stem bark 38-112g; Amomum villosum fruit 38-112g; Schizandra chinensis fruit 31-93g; Angelica polymorpha root 56-168g; Paeonia lactiflora root 75-225g; Cyperus rotundus root 62-187g; Corydalis turtschaninovii tuber 75-225g; Buthus martensii Karsch 31-93g; Salvia miltiorrhiza root 75-225g; Zizyphus jujuba seed 112-337g; Glycyrrhiza uralensis root 62-187g.

Zuo fails to disclose all the limitations recited in claim 1. Specifically, Zuo fails to teach or suggest "Amomum villosum fruit 38-112g; Schizandra chinensis fruit 31-93g; Angelica polymorpha root 56-168g; Paeonia lactiflora root 75-225g; Cyperus rotundus root 62-187g; Buthus martensii Karsch 31-93g." In fact, Zuo teaches away from using the above medicinal materials to curing a withdrawal symptom of addictive drug reliers. Zuo even teaches no suggestion or motivation to use such medicinal materials.

Zuo teaches an extract for abstaining from narcotics, which comprises: 45-60 portions of component A, one or more substances selected from Hominis Placenta, Flower of Datura metel L, toxin of Fugu ocellatus and/or toxin of Naja naja; 15-30 portions of component B; one or more substances selected from Root of Panax ginseng, Ginseng Radix Ferum, Ginseng Radix Coreensis and/or Panacis Quinquefolii Radix; 6-9 portions of component C, one or more substances selected from Root of Aconitum carmichaeli Debx., and/or Skin of Cinnamomum cassia Presl; 30-60 portions of component D, Chelidonium majus L; 9-15 portions of component E, Stem of Corydalis turtschaninovii; component F, 9-15 portions bezoar and/or 0.5-3.0 portions of borneol; 12-15 portions of component G, one or more substances selected from Fruit of Cannabis sativa L. and/or Fruit of Biota orientalis (L) Endl; 6-12 portions of component H, one or more substances selected from Stem of Aipinia officinarum Hance and/or Stem of Zingiber officinale Rosc.; 15-30 portions of component I, red -crowned crane; 15-30 portions of component J, one or more substances selected from Ziziphus jujuba Mill. and/or Fruit of Ziziphus jujuba Mill.; 6-10 portions of component K, one or more substances selected from Glycyrrhiza and Honey-Fried Root of Glycyrrhiza. One of ordinary skill in the art, having read the teaching of Zuo, will not use the the medicinal materials at least comprising "Schizandra chinensis fruit, Angelica polymorpha root, Paeonia lactiflora root, Cyperus rotundus, Buthus martensii Karsch, Amomum villosum fruit." The Chinese medicine of the present invention is prepared with panax ginseng root and aconitum carmichaeli debx root, which is the warm components. The two can nourish spleen and kidney, nourish premordial energy greatly, and consolidate origin, so they are dominant drugs of the prescription. Cinnamomum cassia stem bark, amomum villosum fruit and schizandra chinensis fruit are mixed to assist the panax ginseng root and aconitum carmichaeli debx root to nourish spleen and kidney more effectively, and they three drugs also have efficacies such as relieving diarrhea, arresting sweating, arresting seminal emission and tranquilization. Additionally, angelica polymorpha root and paeonia lactiflora root are mixed therein to assist the basic remedy to nourish female blood, invigorate the circulation of blood, activate the channels, nourish the liver to relieve pain and relieve convulsion. Moreover, salvia miltiorrhiza root and zizyphus jujuba seed are mixed therein to assist the basic remedy to relief fidget, enriching the blood, soothe the nerves, arresting sweating and hidroschesis. Furthermore, glycyrrhiza uralensis root is mixed therein to supplement vital

Application No.: 10/518,728
Docket No. SZ001-04

energy, invigorate the middle-warmer, nourish the lung arrests cough, antidote the poison, assuage pain and concoct the property of the medicine, and to be a conducting drug. Cyperus rotundus root can be used to regulate Qi and solve siltation, regulate menstruation and activate pain. For woman addicts, it can be used to treat menoxenia and amenorrhea. Thus, Zuo teaches away from the invention recited in claim 1 of the present invention.

Even if one assumes Zuo does not teach away from the present invention and can be used as a prior art reference, the combination of Zuo and other cited references still fails to teach or suggest all the limitations of claim 1 as shown below.

Kim teaches a method for treatment of opium, morphine or cocaine dependent human subjects comprising the step of orally administering during the period of drug withdrawal a composition comprising Radix angelica sinensis, Herba pogostemi, Cyperus rotundus and Swquauma manitis pendactilae in unit dosage form. Kim does not teach or suggest what are missing in Zuo, i.e., Radix angelica sinensis and Cyperus rotundus. There is no suggestion or motivation for the person of ordinary skill in the art to combine the two references. Even Zuo and Kim are combined, the combination of Zuo and Kim does not teach or suggest all the limitations of claim 1 and cannot render claim 1 obvious.

Wen teaches a method for treating addiction prevalent in China that six Aconitum carmichaeli; Flow Daturae, Buthus martensii karsch, Cinnbaris, which are herbs of prisoners, and swallow. Wen does not teach or suggest what are missing in the combination of Zuo and Kim, i.e., Buthus martensii karsch and Aconitum carmichaeli. There is no suggestion or motivation for the person of ordinary skill in the art to combine the three references. Even if the Zuo, Wen and Kim are combined, an important component of these compounds is Flow Daturae, which has a chemical component of scopolamine and would be used to restrain the cerebral cortex of the drug relier, produce mild anesthetic effect, stimulate respiratory center, and accelerate the metabolism and excretion of morphine. It is known to the person of ordinary skill in the art, the Flow Daturae L has strong addiction and poisonous side-effect, and its dosage should be strictly controlled. The present invention is a safe Chinese medicine preparation without such poisonous

medicinal materials. Therefore, a combination of Zuo, Kim and Wen does not teach or suggest all the limitations of claim 1 and cannot render claim 1 obvious.

Zhou teaches a caffeine replacement composition, comprising: Ginkgo biloba extract and kudzu extract wherein said Ginkgo biloba extract and said kudzu extract are present at a ratio by weight of said Ginkgo biloba extract to said kudzu extract of between about 0.1 and about 4, and Paeonia lactiflora and Schizandra. Zhou does not teach or suggest what are missing in the combination of Zuo, Kim and Wen, i.e., Paeonia lactiflora and Schizandra. There is no suggestion or motivation for the person of ordinary skill in the art to combine the four references.

Oh teaches a composition for stop smoking comprising Amomum villosum. Oh does not teach or suggest what are missing in the combination of Zuo, Kim ,Wen and Zhou, i.e., Amomum villosum. There is no suggestion or motivation for the person of ordinary skill in the art to combine the five references.

Even the five references are combined, they fail to teach or suggest all the limitations of claim 1. The combination of the five reference teach a compound comprising: one or more substances selected from Hominis Placenta, Flower of Datura metel L, toxin of Fugu ocellatus and/or toxin of Naja naja; Chelidonium majus L; bezoar and/or borneol; one or more substances selected from Fruit of Cannabis sativa L. and/or Fruit of Biota orientalis (L) Endl; one or more substances selected from Stem of Aipinia officinarum Hance and/or Stem of Zingiber officinale Rosc.; Aconitum carmichaeli Debx root; Cyperus rotundus root; Angelica polymorpha root; Cyperus rotundus root; Buthus martensii Karsch; Amomum villosum fruit; Schizandra chinensis fruit; Paeonia lactiflora root; Herba pogostemi; Swquama manitis pendactilae; vermillion and Panax giseng root. Then comparing with this compound, the Chinese traditional medicine preparation of the present invention does not comprises: one or more substances selected from Hominis Placenta, Flower of Datura metel L, toxin of Fugu ocellatus and/or toxin of Naja naja; Chelidonium majus L; bezoar and/or borneol; one or more substances selected from Stem of Aipinia officinarum Hance and/or Stem of Zingiber officinale Rosc.; one or more substances selected from Stem of Aipinia officinarum Hance and/or Stem of Zingiber officinale

Rosc.; Herba pogostemi; Swquama manitis pendactilae. The person of ordinary skill in the art knows that Flower of Datura metel L has strong addiction and poisonous side-effect, and the toxin of Fugu ocellatus and toxin of Naja naja are all neurotoxin which is hard to obtain and costly, and their dosage should be strictly controlled. The person of ordinary skill in the art also knows Fruit of Cannabis sativa L. has component of toadstool choline and hydroxybenzene, which may operate a muscarinic action on central nervous and bring in toxic reaction. Besides, traditional Chinese medicine considers if a person has a long-term freak-out, the abnormal of Qi and Blood may be caused. Lingering of the symptom caused by the long-term freak-out is bound to be of deficiency and siltation. The pathogenic region is in the blood vessel, the pathogenic root is in the kidney and brain. The Chinese medicine preparation of the present invention adapts to the drug relief who has insufficient spleen and kidney, insufficient vital energy and blood, blood stasis and vital energy retardation and evil poison disordering heart. Such pathogenesis belongs to false and true met and cold and heat interwoven, so according to the principle of Chinese medicine dialectical abstinence from drugs, the treatment principle may be adopted which has the efficacy of warming spleen and kidney, benefiting vital energy, enriching the blood, promoting flow of qi and blood circulation, relieving mental stress and abstinence from drugs. Furthermore, the curative effect of the medicinal materials exert optimally, when certain medicinal materials are combined in certain ratio. The Chinese medicine of the present invention is prepared with panax ginseng root and aconitum carmichaeli debx root, which is the warm components. The two can nourish spleen and kidney, nourish premordial energy greatly, and consolidate origin, so they are dominant drugs of the prescription. Cinnamomum cassia stem bark, amomum villosum fruit and schizandra chinensis fruit are mixed to assist the panax ginseng root and aconitum carmichaeli debx root to nourish spleen and kidney more effectively, and they three drugs also have efficacies such as relieving diarrhea, arresting sweating, arresting seminal emission and tranquilization. Additionally, angelica polymorpha root and paeonia lactiflora root are mixed therein to assist the basic remedy to nourish female blood, invigorate the circulation of blood, activate the channels, nourish the liver to relieve pain and relieve convulsion. Moreover, salvia miltiorrhiza root and zizyphus jujuba seed are mixed therein to assist the basic remedy to relief fidget, enriching the blood, soothe the nerves, arresting sweating and hidroschesis. Furthermore, glycyrrhiza uralensis root is mixed therein to supplement vital

Application No.: 10/518,728
Docket No. SZ001-04

energy, invigorate the middle-warmer, nourish the lung arrests cough, antidote the poison, assuage pain and concoct the property of the medicine, and to be a conducting drug.

Furthermore, the IV clinical experiment has proved that the Chinese medicine of the present invention is a safe Chinese traditional medicine for stopping drug addiction. It is not only can be used to control the acute withdrawal symptoms for stopping opium, but also can be used to control prostrated withdrawal symptoms (insomnia, suspense and pain), and obvious improvement is obtained.

Therefore, claim 1 is patentable over Zuo in view of Kim, Wen, Zhou and Oh. Dependent claims 2-10 should also be allowable for at least the same reasons. Accordingly, withdrawal of this rejection is respectfully requested.

Conclusion

Applicant believes this reply is fully responsive to all outstanding issues and places this application in condition for allowance. If this belief is incorrect, or other issues arise, the Examiner is encouraged to contact the undersigned.

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Respectfully submitted,

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Barron & Young Intellectual Property